

The American Clinical Laboratory Association's presentation will begin with an overview of the role of the clinical laboratory in health care technology and focus on several key barriers to making new, high quality, life-saving technologies available to patients in an efficient and effective manner. First, we will address the impact of agency attempts to impose more burdensome regulatory schemes, specifically in areas relating to analyte specific reagents ("ASRs") and multiplex testing, FDA approval, Institutional Review Board requirements, and the coding process including limits on billable units of service. In addition, we will discuss the need for funding and a more substantial governmental role in developing data on the clinical value of new technology, as well as the need for better and more efficient regulatory processes for reimbursement decisions. Currently, the processes for obtaining reimbursement are burdensome and inefficient, with no clear or universal regulatory standards. In addition, the difficulties providers experience in dealing with coverage and payment for new technology are only compounded by the existing difficulties associated with the process for determining payment amounts (e.g., gap filling and crosswalking). We will propose recommendations for alleviating many of these barriers to innovation and the development of new health care technology.